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Amphastar Pharmaceuticals, Inc.
Form 10-Q
May 10, 2018
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF
1934

FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2018

or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF
1934

For the transition period from to

Commission file number 001-36509

AMPHASTAR PHARMACEUTICALS, INC.

(Exact name of Registrant as specified in its charter)

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Delaware
(State or other jurisdiction of
incorporation or organization)

33-0702205
(I.R.S. Employer
Identification No.)

11570 6th Street

Rancho Cucamonga, CA 91730

(Address of principal executive offices, including zip code)

(909) 980-9484

(Registrant's telephone number, including area code)

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes
No

Indicate by check mark whether the Registrant (1) has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the Registrant was required to submit and post such files). Yes No

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer

(Do not check if a smaller reporting company)

Smaller reporting company

Emerging growth company

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If an emerging growth company, indicate by check mark if the Registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

The number of shares outstanding of the Registrant's only class of common stock as of May 3, 2018 was 46,614,060.

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SPECIAL NOTE ABOUT FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, or Quarterly Report, contains “forward-looking statements” that involve substantial risks and uncertainties. In some cases, you can identify forward-looking statements by the following words: “may,” “might,” “will,” “could,” “would,” “should,” “expect,” “intend,” “plan,” “anticipate,” “believe,” “estimate,” “potential,” “continue,” “ongoing” or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these identifying words. Forward-looking statements relate to future events or future financial performance or condition and involve known and unknown risks, uncertainties and other factors that could cause actual results, levels of activity, performance or achievement to differ materially from those expressed or implied by the forward-looking statements. These forward-looking statements include, but are not limited to, statements about:

- our expectations regarding the sales and marketing of our products;
- our expectations regarding our manufacturing and production and the integrity of our supply chain for our products, including the risks associated with our single source suppliers;
- the timing and likelihood of FDA approvals and regulatory actions on our product candidates, manufacturing activities and product marketing activities;
- our ability to advance product candidates in our platforms into successful and completed clinical trials and our subsequent ability to successfully commercialize our product candidates;
- our ability to compete in the development and marketing of our products and product candidates;
- the potential for adverse application of environmental, health and safety and other laws and regulations on our operations;
- our expectations for market acceptance of our new products and proprietary drug delivery technologies, as well as those of our API customers;
- the potential for our marketed products to be withdrawn due to patient adverse events or deaths, or if we fail to secure FDA approval for products subject to the Prescription Drug Wrap-Up program;
- our expectations in obtaining insurance coverage and adequate reimbursement for our products from third-party payers;

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- the amount of price concessions or exclusion of suppliers adversely affecting our business;
- our ability to establish and maintain intellectual property protection for our products and our ability to successfully defend our intellectual property in cases of alleged infringement;
- the implementation of our business strategies, product development strategies and technology utilization;
- the potential for exposure to product liability claims;
- future acquisitions, divestitures or investments, including the anticipated benefits of such acquisitions, divestitures or investments;
- our ability to expand internationally;
- economic and industry trends and trend analysis;
- our ability to remain in compliance with laws and regulations that currently apply or become applicable to our business both in the United States and internationally the impact of global and domestic tax reform, including the Tax Cuts and Jobs Act of 2017;
- the timing for completion of construction and validation at our IMS facility; and
- our financial performance expectations, including our expectations regarding our backlog, revenue, cost of revenue, gross profit or gross margin, operating expenses, including changes in research and development, sales and marketing and general and administrative expenses, and our ability to achieve and maintain future profitability.

You should read this Quarterly Report and the documents that we reference elsewhere in this Quarterly Report completely and with the understanding that our actual results may differ materially from what we expect as expressed or implied by our forward-looking statements. In light of the significant risks and uncertainties to which our forward-looking statements are subject, you should not place undue reliance on or regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified timeframe, or at all. We discuss many of these risks and uncertainties in greater detail in this Quarterly Report and in our Annual Report on Form 10-K for the year ended December 31, 2017, particularly in Item 1A. "Risk Factors." These forward-looking statements represent our estimates and assumptions only as of the date of this Quarterly Report regardless of the time of delivery of this Quarterly Report, and such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. Except as required by law, we undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this Quarterly Report.

Unless expressly indicated or the context requires otherwise, references in this Quarterly Report to “Amphastar,” “the Company,” “we,” “our,” and “us” refer to Amphastar Pharmaceuticals, Inc. and our subsidiaries.

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PART I – FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

AMPHASTAR PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except share data)

	March 31, 2018 (unaudited)	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 54,547	\$ 65,594
Short-term investments	2,826	2,635
Restricted cash and short-term investments	4,155	4,155
Accounts receivable, net	31,883	35,996
Inventories	62,780	63,609
Income tax refunds and deposits	12,194	6,036
Prepaid expenses and other assets	5,661	9,753
Total current assets	174,046	187,778
Property, plant, and equipment, net	191,915	185,339
Goodwill and intangible assets, net	44,850	45,140
Other assets	10,714	8,663
Deferred tax assets	28,257	27,745
Total assets	\$ 449,782	\$ 454,665
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 58,498	\$ 57,555
Income taxes payable	7,983	3,325
Current portion of long-term debt and capital leases	6,061	6,312
Total current liabilities	72,542	67,192
Long-term reserve for income tax liabilities	879	879
Long-term debt and capital leases, net of current portion	39,706	40,844
Deferred tax liabilities	1,425	1,361
Other long-term liabilities	8,126	7,060
Total liabilities	122,678	117,336

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Commitments and contingencies:

Stockholders' equity:

Preferred stock: par value \$0.0001; 20,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock: par value \$0.0001; 300,000,000 shares authorized; 50,471,687 and 46,656,793 shares issued and outstanding as of March 31, 2018 and 50,039,212 and 46,623,581 shares issued and outstanding as of December 31, 2017, respectively	5	5
Additional paid-in capital	316,665	313,891
Retained earnings	69,570	76,235
Accumulated other comprehensive loss	(910)	(2,100)
Treasury stock	(58,226)	(50,702)
Total stockholders' equity	327,104	337,329
Total liabilities and stockholders' equity	\$ 449,782	\$ 454,665

See Accompanying Notes to Condensed Consolidated Financial Statements.

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AMPHASTAR PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited; in thousands, except per share data)

	Three Months Ended March 31,	
	2018	2017
Net revenues	\$ 58,393	\$56,670
Cost of revenues	41,332	33,842
Gross profit	17,061	22,828
Operating (income) expenses:		
Selling, distribution, and marketing	1,721	1,479
General and administrative	10,998	11,338
Research and development	14,260	11,250
Gain on sale of intangible assets	—	(2,643)
Total operating expenses	26,979	21,424
Income (loss) from operations	(9,918)	1,404
Non-operating income (expenses):		
Interest income	124	91
Interest expense	(18)	(191)
Other income, net	782	200
Total non-operating income, net	888	100
Income (loss) before income taxes	(9,030)	1,504
Income tax expense (benefit)	(1,784)	611
Net income (loss)	\$ (7,246)	\$893
Net income (loss) per share:		
Basic	\$ (0.16)	\$0.02
Diluted	\$ (0.16)	\$0.02
Weighted-average shares used to compute net income (loss) per share:		
Basic	46,514	46,069
Diluted	46,514	48,057

See Accompanying Notes to Condensed Consolidated Financial Statements.

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AMPHASTAR PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

(Unaudited; in thousands)

	Three Months Ended March 31,	
	2018	2017
Net income (loss)	\$ (7,246)	\$ 893
Other comprehensive income, net of income taxes		
Foreign currency translation adjustment	1,190	466
Total other comprehensive income	1,190	466
Total comprehensive income (loss)	\$ (6,056)	\$ 1,359

See Accompanying Notes to Condensed Consolidated Financial Statements.

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AMPHASTAR PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited; in thousands)

	Three Months Ended	
	March 31,	
	2018	2017
Cash Flows From Operating Activities:		
Net income (loss)	\$ (7,246)	\$ 893
Reconciliation to net cash provided by operating activities:		
Loss (gain) on disposal and impairment of long-lived assets	598	(2,643)
Depreciation of property, plant, and equipment	3,201	3,100
Amortization of product rights, trademarks, and patents	729	721
Share-based compensation expense	4,666	4,451
Changes in operating assets and liabilities:		
Accounts receivable, net	4,635	920
Inventories	1,441	1,891
Prepaid expenses and other assets	(761)	344
Income tax refund, deposits, and payable	(1,761)	394
Accounts payable and accrued liabilities	2,858	12,327
Net cash provided by operating activities	8,360	22,398
Cash Flows From Investing Activities:		
Purchases and construction of property, plant, and equipment	(12,340)	(7,267)
Sale of intangible assets	4,400	1,000
Purchase of short-term investments	(201)	(1,564)
Maturity of short-term investments	—	1,345
Payment of deposits and other assets	(597)	521
Net cash used in investing activities	(8,738)	(5,965)
Cash Flows From Financing Activities:		
Proceeds from equity plans, net of withholding tax payments	(1,793)	(2,173)
Purchase of treasury stock	(7,624)	(8,203)
Principal payments on long-term debt	(1,411)	(1,342)
Net cash used in financing activities	(10,828)	(11,718)
Effect of exchange rate changes on cash	159	(174)
Net increase (decrease) in cash, cash equivalents, and restricted cash	(11,047)	4,541
Cash, cash equivalents, and restricted cash at beginning of period	67,459	72,354
Cash, cash equivalents, and restricted cash at end of period	\$ 56,412	\$ 76,895

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Supplemental Disclosures of Cash Flow Information:

Interest paid, net of capitalized interest	\$ 532	\$ 390
Income taxes paid	\$ 8	\$ 440

See Accompanying Notes to Condensed Consolidated Financial Statements.

AMPHASTAR PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

Note 1. General

Amphastar Pharmaceuticals, Inc., a California corporation, was incorporated on February 29, 1996 and merged with and into Amphastar Pharmaceuticals, Inc., a Delaware corporation, in July 2004 (together with its subsidiaries, hereinafter referred to as “the Company”). The Company is a specialty pharmaceutical company that primarily develops, manufactures, markets, and sells generic and proprietary injectable, inhalation, and intranasal products, including products with high technical barriers to market entry. Additionally, the Company sells insulin active pharmaceutical ingredient, or API, products. Most of the Company’s products are used in hospital or urgent care clinical settings and are primarily contracted and distributed through group purchasing organizations and drug wholesalers. The Company’s insulin API products are sold to other pharmaceutical companies for use in their own products and are being used by the Company in the development of injectable finished pharmaceutical products. The Company’s inhalation products will be primarily distributed through drug retailers if they are approved and brought to market.

The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements of the Company for the year ended December 31, 2017 and the notes thereto as filed with the Securities and Exchange Commission, or SEC, in the Company’s Annual Report on Form 10-K for the year ended December 31, 2017. Certain information and footnote disclosures normally included in annual financial statements prepared in accordance with generally accepted accounting principles, or GAAP, have been condensed or omitted from the accompanying condensed consolidated financial statements. The accompanying year-end condensed consolidated balance sheet was derived from the audited financial statements. The accompanying interim financial statements are unaudited, but reflect all adjustments which are, in the opinion of management, necessary for a fair statement of the Company’s consolidated financial position, results of operations, comprehensive income (loss) and cash flows for the periods presented. Unless otherwise noted, all such adjustments are of a normal, recurring nature. The Company’s results of operations, comprehensive income (loss) and cash flows for the interim periods are not necessarily indicative of the results of operations and cash flows that it may achieve in future periods.

Note 2. Summary of Significant Accounting Policies

Basis of Presentation

The unaudited condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, and are prepared in accordance with the requirements of the SEC for interim reporting. Effective January 1, 2018, the Company retrospectively adopted Accounting Standard Update, or ASU, No. 2016-15 Classification of Certain Cash Receipts and Cash Payments. Certain amounts in the prior quarter's condensed consolidated balance sheet and condensed consolidated statement of cash flows have been reclassified to conform to the current quarter presentation. This reclassification has no impact on net income or cash flows. All significant intercompany activity has been eliminated in the preparation of the condensed consolidated financial statements. In the opinion of management, the accompanying unaudited condensed consolidated financial statements include all adjustments (consisting only of normal recurring adjustments) necessary to present fairly the consolidated financial position, results of operations, and cash flows of the Company.

The Company's subsidiaries include: (1) International Medication Systems, Limited, or IMS, (2) Armstrong Pharmaceuticals, Inc., or Armstrong, (3) Amphastar Nanjing Pharmaceuticals Inc., or ANP, (4) Nanjing Letop Fine Chemistry Co., Ltd., or Letop, (5) Nanjing Hanxin Medical Technology Co., Ltd., or Hanxin, (6) Nanjing Baixin Trading Co., Ltd., or Baixin, (7) Amphastar France Pharmaceuticals, S.A.S., or AFP, (8) Amphastar UK Ltd., or AUK, and (9) International Medication Systems (UK) Limited, or IMS UK.

AMPHASTAR PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

Use of Estimates

The preparation of condensed consolidated financial statements in accordance with GAAP requires management to make estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and accompanying notes. Actual results could differ from those estimates. The principal accounting estimates include determination of allowances for doubtful accounts and discounts, provision for chargebacks and rebates, provision for product returns, adjustment of inventory to their net realizable values, impairment of long-lived and intangible assets and goodwill, self-insured claims, workers' compensation liabilities, litigation reserves, stock price volatilities for share-based compensation expense, valuation allowances for deferred tax assets, and liabilities for uncertain income tax positions.

Foreign Currency

The functional currency of the Company, its domestic subsidiaries, its Chinese subsidiary, ANP, and its U.K. subsidiary, AUK, is the U.S. dollar, or USD. ANP maintains its books of record in Chinese Yuan. These books are remeasured into the functional currency of USD using the current or historical exchange rates. The resulting currency remeasurement adjustments and other transactional foreign currency exchange gains and losses are reflected in the Company's statements of operations.

The Company's French subsidiary, AFP, maintains its book of record in Euros. Its other Chinese subsidiaries maintain their books of record in Chinese Yuan. Its U.K. subsidiary IMS UK, maintains its book of record in Great Britain Pounds. These local currencies have been determined to be the subsidiaries' respective functional currencies. These books of record are translated into USD using average exchange rates during the period. Assets and liabilities are translated at the rate of exchange prevailing on the balance sheet date. Equity is translated at the prevailing rate of exchange at the date of the equity transactions. Translation adjustments are reflected in stockholders' equity and are included as a component of other accumulated comprehensive income (loss). The unrealized gains or losses of intercompany foreign currency transactions that are of a long-term investment nature are reported in other accumulated comprehensive income (loss). The unrealized gains of intercompany foreign currency transactions that are of a long-term investment nature for the three months ended March 31, 2018 and 2017 were \$0.9 million, and a \$0.5 million, respectively.

Additionally, the Company does not undertake hedging transactions to cover its foreign currency exposure.

Comprehensive Income (loss)

For the three months ended March 31, 2018 and 2017, the Company included its foreign currency translation gain or loss as part of its comprehensive income (loss). Income tax expense of \$0.3 million was allocated to other comprehensive income (loss) for the three months ended March 31, 2018. There was no material income tax expense (benefit) allocated to other comprehensive income (loss) for the three months ended March 31, 2017.

Restricted Cash and Short-term Investments

Restricted cash and short-term investments are collateral required for the Company to effect a standby letter of credit and to qualify for workers' compensation self-insurance and are available to meet the Company's workers' compensation obligations on a current basis, as needed. As of March 31, 2018 and December 31, 2017, restricted cash and short-term investments include \$1.9 million in cash and \$2.3 million in certificates of deposit, respectively. The certificates of deposit have original maturities greater than three months and are classified as short-term investments.

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